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(54) **Making facemasks**

(57) A method of forming a disposable facemask for medical purposes to carry out the administration of gases to a patient provides a relatively soft, pliant surface that readily conforms to the patient's anatomical features in a gas-tight fit. The mask, as formed, comprises two parts; a semi-rigid cone backing to which there is affixed a mask cushion as by solvent bonding, adhesive bonding or mechanical means. The cushion may also be molded directly onto the cone. The cushion is produced by injection molding a thermoplastic compound of a predetermined hardness. The thermoplastic compound is first combined with a blowing agent, and the mixed compound is then fed to an injection moulding machine 18 and heated to break down the blowing agent to give off a gas, such as nitrogen. The heated, plasticised material is then injection molded into a mold 38 of the desired configuration. The molding conditions, such as the venting thereof, are controlled to cause formation of a small, relatively uniform cellular structure within the body of the finished cushion.

FIG. 2

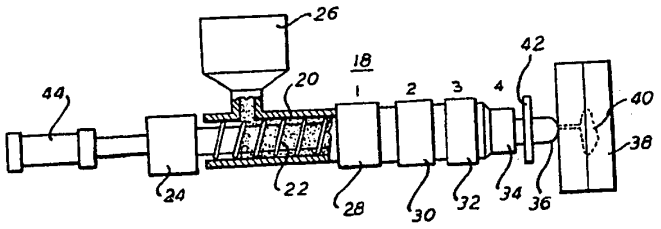

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FIG. 1

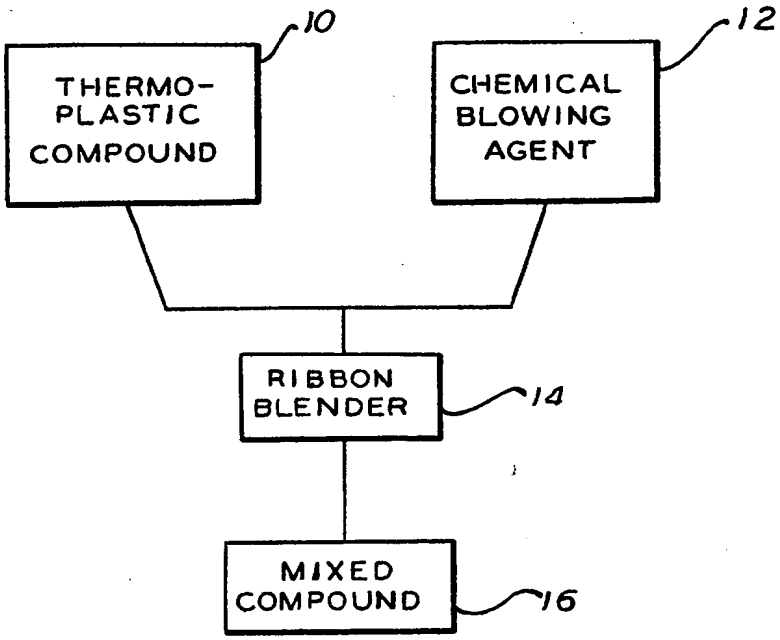


FIG. 2

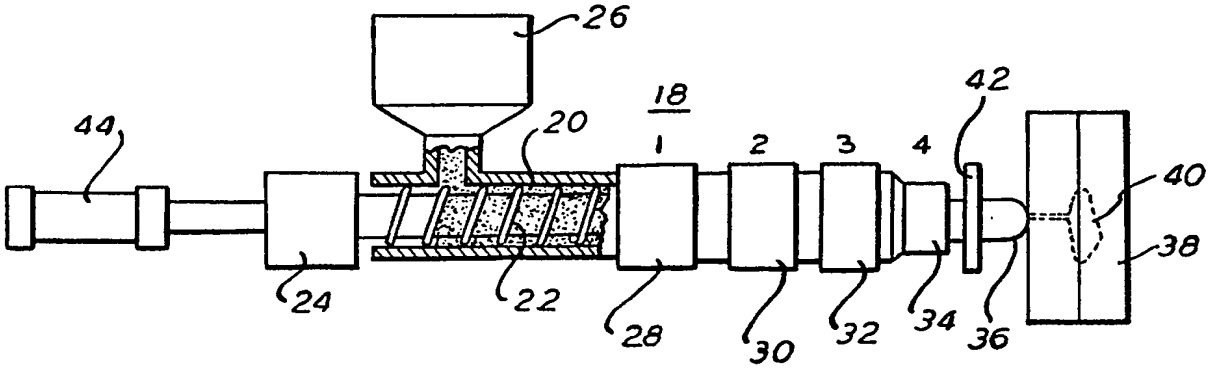


FIG. 3

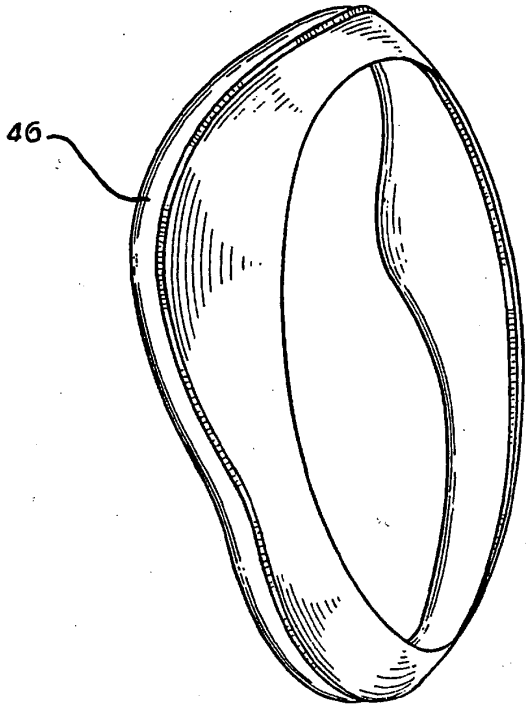
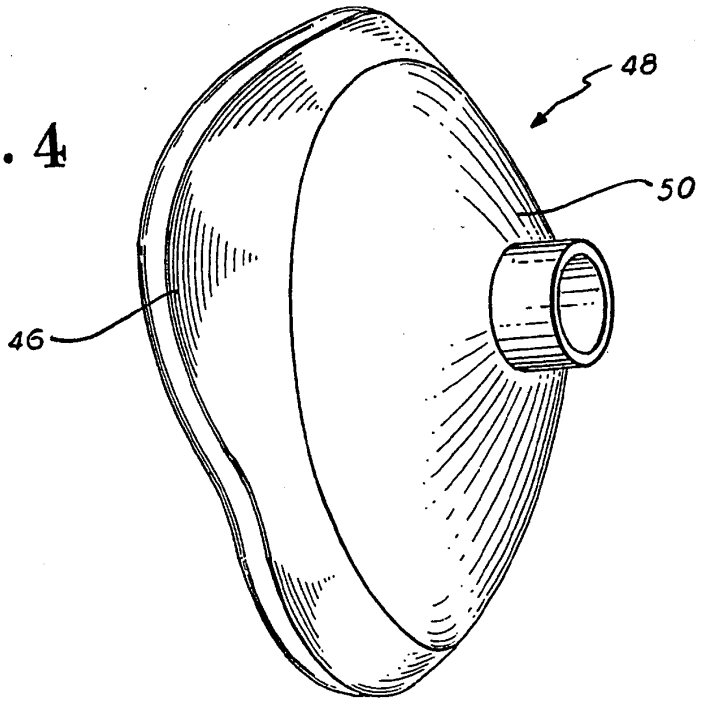


FIG. 4



SPECIFICATION

Disposable face mask

Face masks are used for many different purposes in administering gases to a patient. Typically, such purposes include the administration of inhalant anaesthetics to patients for anaesthetising the same during surgical procedures. Face masks are also included as part of a patient breathing circuit wherein the inhalation of air or oxygen enriched air is assisted by the development of positive pressure within the breathing circuit.

The mask characteristics must be such as to be easily and comfortably conformed to the patient's facial anatomical features despite the obvious unlimited variety of such features. Normally, such masks must provide a relatively gas-tight fit against the face of the patient to prevent escape of gases to the atmosphere that are intended for the patient, yet it is advantageous that such a seal be obtained with a minimum of pressure against the patient, to minimise facial trauma.

Many masks presently on the market are also readily disposable, that is, they are produced and marketed at a price that makes it advantageous for the hospital, or other user, to discard the mask after each use, rather than attempt to clean or sterilise the mask for use on subsequent patients. Disposability, of course, completely alleviates the risk of cross-infection between patients.

Mask producers, therefore, are faced with the production constraints that the eventual mask must be comfortable and pliable against the patient's face, and yet the production procedures must be susceptible of inexpensive mass production capabilities to produce a mask competitive with other commercial disposable products.

Present commercial masks are formed by a variety of methods. One type includes a cushion with a flexible flap which contacts the patient's face, having no sponge or foam characteristics. Another type is a single piece molded flexible mask, again having no viable cushion that conforms to the patient's face.

One further commercial type is produced by an in situ foaming, on a cone backing, of a polyurethane foam that forms a soft cushion. Other masks are believed made with a 'foam' type cushion, however, such are made by cutting a foam to the desired size and bonding the same to a cone backing.

The known masks still have some undesirable features, however, either in the facial compliance or as to the manufacturing procedures which are expensive. Specifically, flexible flaps and single piece masks do not comfortably comply to a patient's anatomical features even though they can be produced very inexpensively, while the known formed in situ masks do have good compliance characteristics but have certain disadvantages in the manufacturing thereof, they require manual trimming and involve the use of chemicals that are undesirable in the environmental surroundings.

According to one aspect of the present invention, a method of producing a patient face mask comprising a mask cushion and a semi-rigid cone comprises the steps of:

(a) combining and mixing uniformly together in a predetermined ratio, plastic molding compound and blowing agent;

(b) heating the combined mixed compound form step (a) to plasticise the compound and to cause the release of gas from the blowing agent;

(c) injection molding the heated mixed compound into a mold having a cavity in the configuration of the desired mask cushion;

(d) controlling the venting of the mold during the injection step;

(e) cooling the molded compound to cause solidification thereof;

(f) removing the thus formed mask cushion from the mold; and

(g) affixing the mask cushion to a semi-rigid cone to produce a completed face mask.

According to a further aspect of the present invention, a disposable face mask adapted to be conformable to a patient's anatomical features comprises an injection molded mask cushion of resilient plastic material having a specific gravity of between about 0.5 and 0.8, said mask cushion being affixed to a semi-rigid thermoplastic cone.

The method defined above overcomes certain difficulties of the aforedescribed known commercial masks in that the foam cushion is injection molded, thus the formed cushion is of the desired dimensions and the labour time and cost of trimming, cutting and the like are significantly reduced.

Also, the finished foam characteristics are such that a cellular foam consistency is covered by a resilient skin and which is soft and pliable and thus readily conforms to the individual features of the patient's face without excessive pressure thereagainst to effect an essentially gas-tight seal.

The overall process is readily adapted to high quantity mass production with a minimum of hand operations but with good consistency of product.

The method achieves these advantages over the various prior art methods and masks made by using prior art methods by the combining of a thermoplastic compound with a blowing agent and heating the mixed compound prior to the injection molding step. The heated, plasticised material, including the released gas, is thereafter injection molded with a mold having the desired cushion dimensions and configuration. The foam cushion is thus formed in the mold by the released gas from the foaming agent, such that the controlled conditions bring about a particular foam characteristic of relatively uniform cellular structure having small cells. A resilient skin is likewise formed about the cellular structure and, acting in conjunction with the cellular foam, presents a soft pliable surface to the patient's face for conformance thereto in a gas-tight relationship.

An embodiment of the invention will now be described, by way of example, reference being made to the Figures of the accompanying diagrammatic drawings in which:-

Figure 1 is a block diagram showing the sequential steps taken to produce a mixed molding compound used in the method of the present invention;

Figure 2 is schematic view of an injection molding machine used to carry out the steps of forming the face mask of the present invention;

Figure 3 is an isometric view of a mask cushion formed in the machine of Figure 2, using a molding compound produced in accordance with Figure 1; and

Figure 4 is an isometric view of a completed mask provided in accordance with the method of the present invention.

In Figure 1 there is shown a block diagram of the sequential steps taken to produce the molding composition used to produce a mask in accordance with the present invention. A source 10 of suitable molding compound is provided for producing the desired composition. Preferably, the molding compound is a thermoplastic material, and the more preferred of such materials is polyvinyl chloride (PVC) having a hardness of about 38 durometer on the Shore A scale. Such grade is commercially available and the further description will refer to PVC as the molding compound for convenience, although it will be recognised that other thermoplastic molding materials may be utilised.

A chemical blowing agent source 12 is also provided which supplies a chemical blowing agent for mixing in predetermined properties with the molding compound to produce a composition for use with this invention. Azodicarbonamide is the most widely used chemical blowing agent. One such suitable chemical blowing agent is Kempor 200, sold commercially by Stepan Chemical Company and which gives off nitrogen and other gases under certain molding conditions. That particular blowing agent is available in powder form and, therefore, is very convenient for mixing with the molding compound which is also preferably in powder form. It is also possible to utilise a blowing agent in the form of liquids, also commercially available, however, it is considerably more difficult to obtain a suitable uniform mixture of the same with a molding compound in a powder form.

With the preferred ingredients, therefore, the PVC molding compound powder is mixed with the blowing agent powder in a commercially available ribbon blender 14 in predetermined proportions, with standard grade PVC powder and the aforementioned Kempor 200 blowing agent, a mixing ratio in the range of one part blowing agent to 99 parts molding compound is utilised and which produces excellent results, however, on a weight percent basis, adequate results have been achieved when the blowing agent percent ranges from about .25% to about 1.5% by weight.

The mixed compound, of uniform consistency and mixing, is desired from the ribbon mixer 14 as shown at 16. The mixed compound is now ready for use with an injection molding machine in a manner to be described.

Referring now to Figure 2, there is illustrated an injection molding machine 18 in a schematic form. The injection molding machine 18 comprises a main barrel 20 in which is positioned a screw 22 which is adapted to rotate by means of motor 24. Molding compound is gravity fed into the barrel 20 from hopper 26 where a supply of such compound is retained. In the present invention of course, the molding compound is the mixed compound from 16 (Figure 1). A plurality of heating zones 1-4 and numbered respectively 28, 30, 32 and 34 are positioned between that portion of the main barrel 20 receiving mixed compound from hopper 26 and the nozzle 36 from which the mixed compound is ultimately injected into a mold 38. The mould 38 has a suitably shaped cavity 40 in the form of the mask cushion which is desired to be formed. The mold 8 varies, of course, in accordance with the particular mask cushion being produced, ie. adult size, childrens size, etc. A shut-off valve 42 is also included at the end of the heating zones and prior to the injection of the mixed compound from nozzle 36.

At the opposite end of the barrel 20 from nozzle 36, there is located a hydraulic cylinder 44 which is adapted to move the screw 22 when activated, as will be later explained.

In the operation of the injection molding machine 18, the mixed compound in the hopper 26 provides a continuous feed of the same into the barrel 20. The heating zones are intially brought up to temperature in progressively higher temperature to heat the mixed compound as it progresses towards nozzle 36. With PVC compound and the preferred blowing agent, the heating zones may be set such that zones 28, 30, 32 and 34 are respectively at temperatures of about 260°F, 260°F, 320°F and 350°F. A typical injection cycle takes about 20 seconds and the temperature of the mold 38 is about 60°F to about 120°F, although the mold temperature is not a particularly critical value.

The cycle is initiated as mold 38 is closed. The hydraulic cylinder 44 thereupon moves the screw 22 forward toward mold 38. Screw 22 acts like a plunger and forces the mixed compound within barrel 20 toward the mold 38. The valve 42 opens and the heated mixed compound is thus forced into the mold cavity 40 into the configuration of a mask cushion.

At the end of the forward stroke of hydraulic cylinder 44 and screw 22, the shut-off valve 42 again closes and the screw 22 rotates to force additional mixed compound from the hopper 26 in the direction of the mold 38 within the barrel 20. As the barrel 20 fills with mixed compound, the screw 22 rotates itself backwards and causes an internal backpressure on the mixed compound as the screw 22 moves back to its original position. The controlled backpressure exerted by the screw 22 on the mixed compound serves to pack the compound tightly and also serves to prevent the escape of gas that is being released from the blowing agent backward toward hopper 26. At the end toward the mold 38, the valve 42 is, of course, now shut so that no gas or plasticised material is lost or leaked into the mold 38.

As the mixed compound is compacted in the end of the barrel toward the mold 38, the compound passes through the heating zones 28, 30, 32 and 34. As the mixed compound approaches the final heating zone 34, it becomes plasticised and the particular blowing agent breaks down as a result of the pressure and temperature conditions and gives off a gas (in the case of the preferred blowing agent, that

gas is nitrogen). The gas goes into solution with the plasticised material and remains in such form until the next injection step.

As the cycle is completed, the plasticised material that has been injected into the mold 38 cools, the mold 38 is opened and the thus formed mask cushion is removed.

The mold cavity 40 is vented to allow the escape of a predetermined amount of 'freed' gas to achieve the desired mask cushion consistency. The amount of controlled venting determines the cellular size and therefore determines the pliability of the cushion. Too much venting results in coarse cell structure resulting in loss of pliability, while too little venting creates very fine, almost non-existent cell size, again result in an absence of pliability. The venting is determined by testing the particular mold cavity and setting and adjusting the amount of venting such that the desired cellular structure is achieved which exhibits soft pliable characteristics.

The resulting cushion 46 removed from the mold 38 is shown in Figure 3. In the preferred form, the cushion 46 has a specific gravity of between about 0.5 to about 0.8 and with a base compound of 38 durometer (Shore A). The pliability exhibits adequate compressibility and is readily adapted to conform to the facial anatomical features of a patient.

The final patient mask 48, Figure 4 is produced by affixing the foam cushion 46 to a cone 50. The cone 50 is formed by conventional methods, such as injection molding and is preferably of a thermoplastic material such as PVC. The cone 50 may be opaque, transparent or translucent, depending upon the material used. Preferably, the cone 50 is made of such a material (PVC) such that the cone 50 may, if desired, be solvent bonded to the foam cushion 46. Alternatively, the cushion 46 and cone 50 may be affixed together by mechanical means or through bonding by means of a suitable adhesive, or by inserting the cone into the mold and molding the cushion to it (insert molding).

Thus, there is produced a face mask having particularly advantageous softness characteristics by a judicious selection of materials and conditions, such that a foam cushion is injection molded and which is affixed to a cone backing to produce a facemask that is inexpensive to produce, yet which is easily adaptable to conform to the facial anatomical features of a patient. The cushion support is kept to a minimum through the cone backing and which allows its soft characteristic to be fully utilised in molding itself to the patient features with a minimum of pressure on the face mask, such as to reduce the possibility of patient facial trauma.

CLAIMS

1. A method of producing a patient face mask comprising a mask cushion and a semi-rigid cone comprising the steps of:

(a) combining and mixing uniformly together in a predetermined ratio, plastic molding compound and blowing agent;

(b) heating the combined mixed compound from step (a) to plasticise the compound and to cause the release of gas from the blowing agent;

(c) injection molding the heated mixed compound into a mold having a cavity in the configuration of the desired mask cushion;

(d) controlling the venting of the mold during the injection step

(e) cooling the molded compound to cause solidification thereof;

(f) removing the thus formed mask cushion from the mold; and

(g) affixing the mask cushion to a semi-rigid cone to produce a completed face mask.

2. A method as set forth in claim 1 wherein said molding compound is a thermoplastic elastomer.

3. A method as set forth in claim 1 wherein said molding compound is polyvinyl chloride.

4. A method as set forth in claims 2 or 3 wherein said blowing agent is azodicarbonamide and is present in the resultant mixture in a range from about .25% to about 1.5% by weight.

5. A method as set forth in claim 4 wherein said heating step takes place at a temperature in excess of 300°F.

6. A method as set forth in claim 1 wherein said affixing step comprises solvent bonding the mask cushion to a polyvinyl chloride cone.

7. A method set forth in claim 1 wherein the mask cushion is insert molded to said cone.

8. A disposable face mask adapted to be conformable to a patient's anatomical features comprising an injection molded mask cushion of resilient plastic material having a specific gravity of between about 0.5 and 0.8, said mask cushion being affixed to a semi-rigid thermoplastic cone.

9. A disposable face mask as set forth in claim 8 wherein said plastic material is a thermoplastic elastomer.

10. A disposable face mask as set forth in claim 8 wherein said plastic material is polyvinyl chloride.

11. A disposable face mask as set forth in claims 8 or 9 wherein said mask cushion is solvent bonded about its outer peripheral surface to said thermoplastic cone.

12. A disposable face mask as set forth in claims 8 or 9 wherein said mask cushion is insert molded to said thermoplastic cone.

13. A method of producing a patient face mask comprising a mask cushion and a semi-rigid cone substantially as hereinbefore described with reference to Figures 1 to 4 of the accompanying drawings.

14. A disposable face mask constructed and arranged substantially as hereinbefore described with reference to and as illustrated in Figure 4 of the accompanying drawings.

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FIG. 1

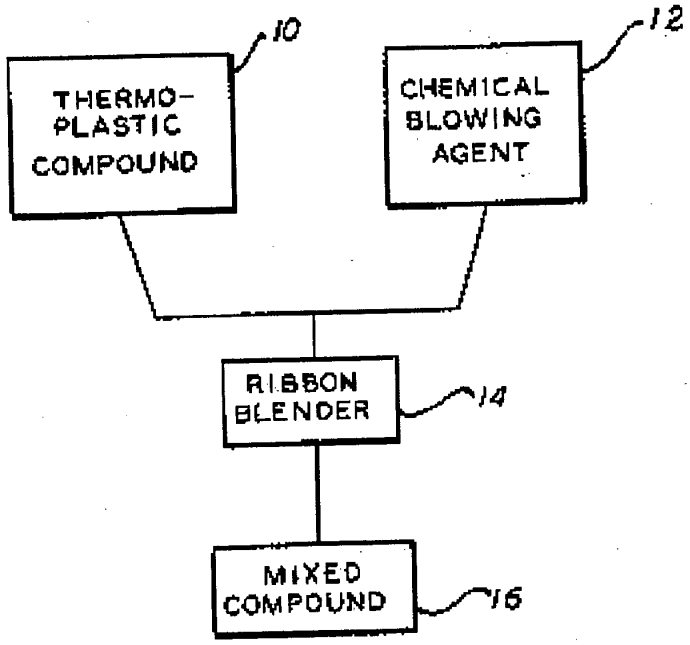

FIG. 2

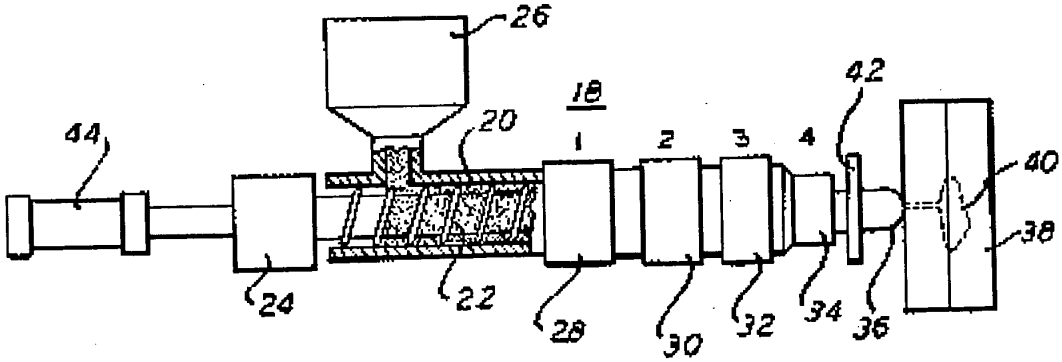

FIG. 3

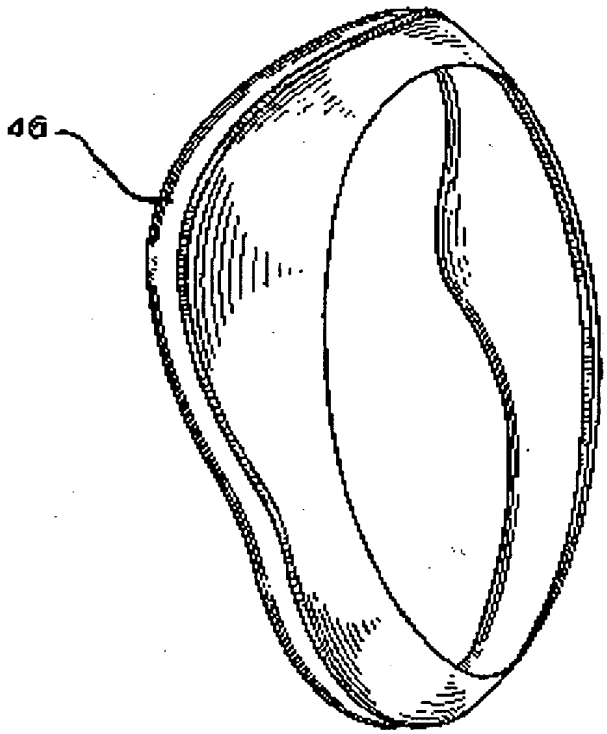

FIG. 4